

Message Text

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ORIGIN SCI-06

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DRAFTED BY SCI/ SA: MBEAUBIEN: LTG

4/2/73 EXT 21698

APPROVED BY SCI/ SA: MBEAUBIEN

HEW/ FDA: HBAER (PHONE)

EW/ FDA: LSHELTON (PHONE)

HEW/ OIH: JKING (PHONE)

ARA/ APU: TTONKIN

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R 031919 Z APR 73

FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES

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E. O. 11652: GDS

TAGS: TPHY, TBIO, AR

SUBJECT: REQUIREMENT FOR WHOOPING COUGH BACILLUS

REF: BUENOS AIRES 2055

1. BUREAU OF BIOLOGICS, HEW/ FDA, INDICATES IT ABLE TO PROVIDE FREEZE- DRIED PERTUSSIS CULTURE STOCK. HOWEVER IT FEELS THAT SPECIFIC MANUFACTURING REQUIREMENTS SHOULD BE OBTAINED BY ARGENTINE MANUFACTURER (IBA) THROUGH COMMERCIAL CHANNELS.

2. FYI. FDA POINTS OUT THAT CONSIDERABLE HAZARDS POSSIBLE FROM VACCINE IF NOT PREPARED ACCORDING TO VERY CAREFUL PROCEDURES AND PROCESS. WHILE IT FULLY AWARE THESE REQUIREMENTS, IT DOES NOT FEEL IT SHOULD ADVISE ON THESE SINCE ONUS OF INFERIOR OR HAZARDOUS PRODUCT RESULTING FROM FAILURE TO OBSERVE PROPER PROCESSING MIGHT BE PLACED ON USG AND FDA. END FYI.

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3. AMONG LICENSED MANUFACTURERS IN U. S. FOR PERTUSSIS VACCINE ARE: LEDERLE, PARKE-DAVIS, ELI LILLY, MERRELL-NATIONAL, AND WYETH. IBA MAY BE ABLE TO WORK OUT AGREEMENT WITH ONE OF THESE FOR NECESSARY PROCESSING REQUIREMENTS AND ADVICE. CULTURE STOCK MIGHT ALSO BE OBTAINED FROM SAME SOURCE.

4. IF IBA WISHES CULTURE STOCK FROM BUREAU OF BIOLOGICS, IT SHOULD MAKE FORMAL REQUEST TO DR. HARRY MEYER, DIRECTOR BUREAU OF BIOLOGICS, FOOD AND DRUG ADMINISTRATION, 5600 FISHERS LANE, ROCKVILLE, MARYLAND 20852. RUSH

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*** Current Handling Restrictions *** n/a

*** Current Classification *** LIMITED OFFICIAL USE

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